

REMARKS

Status of the Claims

Claims 16, 18, 31, 34, 36 and 38-45 are currently pending in the application. Claims 16, 18, 31, 34, 36 and 38-45 stand rejected. Claims 16, 18, 31, 36, 39 and 43 have been amended as set forth herein without prejudice or disclaimer. The amendments of the claims are to remove subject matter, *e.g.* rhamnam sulfate and heparin sulfate. No new matter has been added by way of the present amendments. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 16, 18, 31, 34, 36 and 38-45 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action of May 16, 2007, at pages 4-10). Applicants traverse the rejection as set forth herein.

The Examiner's analysis of the *Wands* factors focuses on the lack of enablement of all "acidic macromolecular substances" encompassed by the claims. The Examiner emphasizes that the claims may be read to encompass any cell type, and any PCR inhibitor, including DNA itself and inhibitors found in "ancient" DNA samples as well as modern DNA samples. The Examiner cites many references, at pages 6-8, disclosing that heparin, and other acidic polysaccharides, are well known in the art to be an inhibitor of PCR reactions.

Although Applicants do not agree that the present claims lack enablement support in the specification, to expedite prosecution, claims 16, 18, 31 and 36 have been amended herein without prejudice or disclaimer to remove rhamnam sulfate. Additionally, claims 39 and 43 have

been amended herein without prejudice or disclaimer to remove the terms "dextran, carrageenan, heparin" and "pectin."

The Examiner states that the claims lack enablement for enhancement of PCR reactions. However, only claims 39 and 43 recite the phrase, "wherein said water-soluble acidic macromolecular substances or water-soluble salts thereof enhance DNA synthesis reactions." Claims 16, 18, 31, 34, 36, 38, 40-42, 44 and 45 do not recite this phrase. That is, claims 16, 18, 31, 34, 36, 38, 40-42, 44 and 45 are directed to "a DNA synthesis reaction" or kit. Thus, the Examiner is requiring enablement of an element not recited in claims 16, 18, 31, 34, 36, 38, 40-42, 44 and 45.

Page 27, line 22, and page 62, Table 2, of the specification discloses the use of heparin and its effect in enhancing DNA synthesis under the reaction conditions specified in Examples 1-3. Thus, the Examiner's statement that the specification lacks any support or proof of enhancement of PCR using heparin is without basis. Additional proof of enablement of the other compounds listed in the "non-enabled" category can be found in Example 8, (Table 2), showing enhancement of PCR by addition of dextran sulfate. Furthermore, the benefits of addition of polyacrylic acid on PCR are clearly disclosed in Example 15 (Table 10). The benefits of hyaluronic acid are disclosed at Example 16 (Table 11). The benefits of dermatan sulfate, polystyrene sulfate and polyvinyl sulfate are disclosed at Example 16 (Table 12).

Therefore, the Examiner's rejection is inconsistent on its face because the Examiner states there is enablement for some compounds (sulfated-fucose-containing polysaccharides, sodium alginate, sodium polyglutamate, sodium polyacrylate and κ -carrageenan) but not others (dextran sulfate, rhamnan sulfate, dermatan sulfate, heparin sulfate, hyaluronic acid,

polyglutamic acids, polyacrylic acids, polyvinyl sulfates, polystyrene sulfates or their salts and heparin) referring to the same data and same support found in the present specification for all of the named substances.

Finally, the Examiner is applying an incorrect standard of proof of enablement. That is, rather than applying a "substantial evidence" standard, the Examiner appears to be requiring "clear and convincing evidence" of the effectiveness of Applicants' invention as claimed. That this is true is highlighted by the continued rejection of these claims in spite of the large amount of data disclosed in Examples 1-24 in the present specification.

For at least these reasons, reconsideration and withdrawal of the enablement rejection of claims 16, 18, 31, 34, 36 and 38-45 are respectfully requested.

Rejections Under 35 U.S.C. § 102(a)

Claims 16, 18, 40-42 and 45 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Al-Soud et al., *Appl. Environ. Microbiol.*, 64:3748-3753, 1998 (hereinafter, "Al-Soud et al."), as evidenced by Wikipedia definition of heparin. (See, Office Action, at pages 10-11). Applicants traverse the rejection as set forth herein.

The Examiner states that Al-Soud et al. disclose a DNA synthesis reaction comprising all of the components recited in claims 16 and 18. Al-Soud et al., according to the Examiner, disclose polymerization reactions using meat solutions and meat is known to contain heparin sulfate, citing "Wikipedia."

Although Applicants do not agree that the presently claimed invention is anticipated by the disclosure of Al-Soud et al., to expedite prosecution, claims 16 and 18 have been amended herein without prejudice or disclaimer to remove the element "heparan sulfate."

Dependent claims 40-42 and 45 are not anticipated as, *inter alia*, depending from non-anticipated base claims, amended claims 16 and 18.

Reconsideration and withdrawal of the anticipation rejection of claims 16, 18, 40-42 and 45 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Demeke et al. & Barnes

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Demeke et al., *Biotechniques*, 12:332 and 334, 1992 (hereinafter, "Demeke et al.") in view of Barnes, U.S. Patent No. 5,436,149 (hereinafter, "Barnes"). (*See*, Office Action, at pages 11-12, paragraph 14). Applicants traverse the rejection as hereinafter set forth.

The Examiner states at page 3, paragraph 7, that the arguments presented in the amendment of February 20, 2007 were unpersuasive because claim 39 does not recite "any particular polysaccharide concentration which has the property of enhancing a DNA amplification" reaction. The Examiner points out that PCR combining carageenan, pectin, dextran sulfate or heparin with a DNA polymerase having a 3' → 5' exonuclease activity is obvious over the combination of the disclosure of Barnes with the disclosure of Demeke et al.

Although Applicants do not agree that the presently claimed invention is obvious in light of the cited disclosures, to expedite prosecution, claim 39 has been amended without prejudice or disclaimer to remove the terms "carageenan," "pectin," "dextran sulfate" and "heparin."

Reconsideration and withdrawal of the obviousness rejection of claim 39 are respectfully requested.

Tasa et al. & Barnes

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Tasa et al., *Meth. Mol. Cell. Biol.*, 5:122-124, 1995 (hereinafter, "Tasa et al.") and Barnes. (*See*, Office Action, at page 12, paragraph 15). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Tasa et al. do not disclose a DNA polymerase having 3' to 5' exonuclease activity, Barnes discloses a composition comprising two DNA polymerases, one of which has such activity. Thus, in combination, the Examiner states that the two references make obvious the subject matter of claim 39 since Barnes states that such DNA polymerase activity is useful for amplifying long DNA targets.

Although Applicants do not agree that the presently claimed invention is obvious in light of the cited disclosures, to expedite prosecution, claim 39 has been amended without prejudice or disclaimer to remove the terms "carageenan," "pectin," "dextran sulfate" and "heparin."

Reconsideration and withdrawal of the obviousness rejection of claim 39 are respectfully requested.

Demeke et al. & Barnes & Strategene Catalog

Claims 43 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Demeke et al. and Barnes, and further in view of the Strategene Catalog. (*See*, Office Action, at page 13, paragraph 16). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Demeke et al. and Barnes disclose the reaction composition of claim 39, they do not disclose the idea of placing such reagents in kits. However, the Examiner states that the Strategene Catalog discloses kits and provides a general motivation for combining into a kit reagents for conducting such a reaction.

Although Applicants do not agree that the presently claimed invention is obvious in light of the cited disclosures, to expedite prosecution, claim 43 has been amended without prejudice or disclaimer to remove the terms "carageenan," "pectin," "dextran sulfate" and "heparin."

Claim 44 depends from claim 43. The Examiner has provided no independent reasoning for the rejection of dependent claim 44. Thus, dependent claim 44 is believed to be non-obvious for, *inter alia*, depending from a non-obvious base claim, amended claim 43.

Reconsideration and withdrawal of the obviousness rejection of claims 43 and 44 are respectfully requested.

Tasa et al. & Barnes & Strategene Catalog

Claims 43 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Tasa et al. and Barnes, and further in view of the Strategene Catalog. (*See*, Office Action, at page 13, paragraph 17). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Tasa et al. and Barnes disclose the reaction composition of claim 39, they do not disclose the idea of placing such reagents in kits. However, the Examiner states that the Stratagene Catalog discloses kits and provides a general motivation for placing reagents in a kit for conducting such a reaction.

Although Applicants do not agree that the presently claimed invention is obvious in light of the cited disclosures, to expedite prosecution, claim 43 has been amended without prejudice or disclaimer to remove the terms "carageenan," "pectin," "dextran sulfate" and "heparin."

Claim 44 depends from claim 43. The Examiner has provided no independent reasoning for the rejection of dependent claim 44. Thus, dependent claim 44 is believed to be non-obvious for, *inter alia*, depending from a non-obvious base claim, amended claim 43.

Reconsideration and withdrawal of the obviousness rejection of claims 43 and 44 are respectfully requested.

Rejections Under the Obviousness-Type Double Patenting Doctrine

Claims 16, 18, 31, 36, 39 and 43 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-17 of U.S. Patent Application Serial No. 10/435,633 (hereinafter referred to as "the '633 application"). (See, Office Action, at page 10, paragraph 16). Although the Examiner claims the '633 is not abandoned, the Examiner's attention is drawn to the transaction history report of the '633 application which shows that a non-final Office Action was mailed on November 17, 2006. The statutory deadline for responding to the November 17, 2006 Office Action was May 17, 2007.

Thus, the '633 application is not pending. Therefore, Applicants note again that the '633 application has been permitted to become abandoned. As such, this rejection is moot.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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